Document Type: Implied Consent Form - Oncologist

Title: A pilot randomized controlled trial of a patient-centered communication tool (UR-GOAL) for older patients with acute myeloid leukemia, their caregivers, and their oncologists

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ONCOLOGIST IMPLIED CONSENT

A pilot randomized controlled trial of a patient-centered communication tool (University of Rochester-Geriatric Oncology Assessment for acute myeloid Leukemia or UR-GOAL) for older patients with acute myeloid leukemia, their caregivers, and their oncologists

Principal Investigator: Dr. Kah Poh (Melissa) Loh

This form describes a research study that is being conducted by Dr. Kah Poh (Melissa) Loh from the University of Rochester's Division of Hematology and Oncology, Department of Medicine.

The purpose of this study is to assess the preliminary efficacy of a communication tool (UR-GOAL) versus usual care in improving shared decision making and communication between older patients with acute myeloid leukemia (AML) and their oncologists.

If you decide to take part in this study, you will be asked to:

- Complete questionnaires regarding decision-making and disease understanding.
- Participate in an audio-recorded interview during which we will explore your preferences and feedback regarding the communication tool and communication with the patient.

Duration of Study

Your participation in this study will last up to three years.

Sponsor Support

The University of Rochester is receiving funding from the *Conquer Cancer®, the American Society of Clinical Oncology (ASCO),* and the *American Cancer Society®* for conducting this research study.

Costs

There will be no cost to you to participate in this study.

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Payments
You will not be paid for participating in this study

Benefits of Participation
You might not benefit from being in this research study.

Risks of Participation
The study has minimal risk. While we will make every effort to keep the information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. There is a risk of loss of confidentiality and privacy because we will collect personal data (demographics) from you. Protected personal data will be kept as confidential as they can be but complete confidentiality cannot be guaranteed. Before you agree to participate, there are some additional things you should know about the study.

Use of E-mail for Communication in Research
You will receive communication about this study via email.
Email communications will be used to complete baseline and post-intervention surveys, notify clinicians of enrolled patients, schedule study visits, and schedule your interview.
Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the research team. Your participation indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email.
Email communications between you and the research team may be filed in your research record.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
Sometimes researchers need to share information that may identify you with people that work for the University. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented publicly at meetings or in publications, but your name or identifying information will not be used.
Audio-recorded interviews will be transcribed by a professional transcription service called ExecuScribe. Both the audio-recorded interviews and interview transcripts will be kept for 7 years after the study and all reports and publications are complete.

In order to collect study information, we have to get your permission to use and give out your personal information. We will keep your information for 7 years after study completion. Your information will be destroyed after.

The study doctor and study coordinators receive your personal information which could include:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Your information maybe be given to:

- The Department of Health and Human Services
- The University of Rochester
- ExecuScribe (for the purpose of transcription)

Non-identifying information that has already been gathered may need to be used and given to others for the following purposes:

- To replicate the research/copy the study
- To study the results
- To see if the research was done right

Voluntary Participation

Taking part in this research is not a part of your duties and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. If you do withdraw from this study, the information you have already provided will be kept confidential.

For more information or questions about this research you may call Dr. Kah Poh Loh at 585-276-4353, or the study coordinator at (585) 602-5082.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;

- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this website at any time.

If you agree to participate in this study and would like to consent to participate as an oncologist, please press “I agree” below:

- I agree
- I do not agree